

NOTICE OF INTENT

Department of Health Board of Medical Examiners

Complaints and Investigations; Adjudication and Practice-Site Visits; Practice Performance Reviews
(LAC 46:XLV.Chapters 97, 99 and 80)

Notice is hereby given that in accordance with the Louisiana Administrative Procedure Act, La. R.S. 49:950 et seq., and pursuant to the authority vested in the Louisiana State Board of Medical Examiners (board) by the Louisiana Medical Practice Act, R.S. 37:1261-1292, as amended by Act 599 of the 2018 Session of the Louisiana legislature, the board intends to amend its rules of procedure governing complaints and investigations (Chapter 97), adjudication (Chapter 99) and practice, site visits; practice performance reviews (Chapter 80). Among other items, the proposed changes: expand the application of the rules to include allied health care practitioners regulated by the board (§9701.A), define additional terms (§9703.A) for allied health care practitioner, applicant, compliance counsel, director of investigations, independent counsel, licensee, records or files of the case, and amend several existing definitions. The proposed changes also provide: for complaint origination, complainant confidentiality and routine regulatory functions (§9705.A, D and E); the instances in which the board shall initiate a preliminary review to determine if cause exists for formal investigation (§9709.A); for files and records related to a complaint which the board may obtain (§9709.B); for records or files of the case (§§9703.A and 9709.C); for the duration of a preliminary review and extensions (§9709.D); that if the board intends to use records from any prior investigation, the licensee shall be notified and the records included within the records or files of the case (§9711.D); for individuals who may attend conferences (§9711.G.1); for disciplinary dispositions, provide that prior to offering a consent order to a licensee the board shall make all files and records pertinent to the case before the board available, and for related notice and procedure (§9713.C.2); for general definitions for adjudication purposes (§9902); for notice to a licensee of the right to face any complainant at an administrative hearing and for exceptions relative to complainant anonymity (§9905.C); that upon filing of a formal administrative complaint all records or files of the case regarding the complaint shall be made available through full discovery (§9916.A.3); that any potential exculpatory evidence shall be disclosed whether or not requested and whether or not reduced to recorded or documentary form (§9916.A.4); the procedure for initiation of site visits, practice performance reviews or requesting medical records from licensees who are not subject to an active investigation (§§8801-8003); and make other changes made necessary by the passage of time and/or for purposes of implementation. The proposed amendments are set forth below.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part XLV. Medical Professions

Subpart 3. Practice

Chapter 80. Site Visits; Practice Performance Reviews

§8001. Scope of Chapter

A. The rules of this Chapter govern the board's initiation of site visits and practice performance reviews prescribed or authorized by the laws or rules administered by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B); 37:1285.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 46:

§8003. Initiation of Site Visit; Requesting Medical Records

A. Prior to conducting a site visit or requesting medical records from an individual licensed by the board who is not the subject of an active investigation, the executive director shall, following discussion in executive session, request approval to conduct the site visit or make the records request by a duly adopted motion by two-thirds vote of the board.

B. The executive director shall include in the request for approval the basis upon which the site visit or records request is warranted, the number of records to be requested, if applicable, the date, time and anticipated length of the proposed site visit, and the dates of any previous site visits.

C. The board shall not disclose the identity of any person included in the request for approval to conduct a site visit or record request.

D. The provisions of this section shall apply to practice performance reviews of physicians practicing telemedicine.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270, 37:1285.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 46:

Subpart 5. Rules of Procedure

Chapter 97. Complaints and Investigations

§9701. Scope of Chapter

A. The rules of this Chapter govern the board's processing of complaints and investigations relative to the laws governing physicians, allied health care practitioners, as defined herein, and applicants seeking to practice as a physician or allied health care practitioner, as well as other state and federal laws to which physicians and allied health care practitioners are subject and the board's rules. These rules are intended to supplement, but not replace, any applicable provision of the Louisiana Administrative Practice Act, R.S. 49:950 et seq. regarding the disciplinary process and procedures. To the extent that any Rule of this Part is in conflict therewith, the provisions of the Louisiana Administrative Procedure Act shall govern.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292 and 37:1270(A)(5) and 37:1285.2.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2627 (December 2015), amended by the Department of Health, Board of Medical Examiners, LR 46:

§9703. Definitions

A. As used in this Chapter, the following terms shall have the meanings specified.

Allied Health Care Practitioner—an individual, other than a physician, authorized by the board to practice in this state including, but not limited to: a licensed acupuncturist, pursuant to R.S. 37:1360; an athletic trainer pursuant to R.S. 37:3301-3312; a clinical exercise physiologist pursuant to R.S. 37:3421-3433; clinical laboratory personnel pursuant to R.S. 37:1311-1329; a genetic counselor pursuant to R.S. 37:1360.101-1360.111; a medical psychologist pursuant to R.S. 37:1360.51-1360.72; a midwife pursuant to R.S. 37:3240-3257; an occupational therapist or occupational therapy assistant pursuant to R.S. 37:3001-3014; a perfusionist pursuant to R.S. 37:1331-37:1343; a physician assistant pursuant to R.S. 37:1360.21-1360.38; a podiatrist pursuant to R.S. 37:611-628; a polysomnographic technologist or technician pursuant to R.S. 37:2861-2870; a private radiological technologist pursuant to R.S. 37:1292; a licensed respiratory therapist pursuant to R.S. 37:3351-3361; as well as any other an individual who holds any form of health care practitioner license,

certificate, registration or permit that the board is authorized to issue, other than as a physician.

Applicant—an individual who has applied to the board for lawful authority to engage in the practice of medicine or that of an allied health care practitioner in this state.

* * *

Compliance Counsel—a Louisiana licensed attorney designated to assist the board to observe and comply with the rules of this Chapter and corresponding laws, who is independent of the DOI and the licensee and has not participated in the review, investigation, recommendations for disposition or prosecution of the case; provided, however, that compliance counsel may attend meetings between the DOI and a licensee held pursuant to this Chapter for purposes of compliance.

Complaint—any information, claim or report of whatsoever kind or nature received or obtained by the board, or initiated by the board on its own motion pursuant to R.S. 37:1285.2(A), that alleges or may indicate a violation of the law by a licensee or an applicant.

Director of Investigations (DOI) or sometimes also referred to in this Part as the *Investigating Officer*—a physician possessing the qualifications specified by R.S. 37:1270A(9), appointed by the board to serve as the lead investigator for any complaint.

Independent Counsel—an individual licensed to practice law in this state and who is appointed pursuant to §9921.D of these rules to perform such duties as may be required pursuant to R.S. 37:1285.2 and other provisions of this Part.

* * *

Law (or the Law)—unless the context clearly indicates otherwise, the Louisiana Medical Practice Act, R.S. 37:1261-1292, the Practice Acts governing allied health care practitioners, other applicable laws administered by the board and the board's rules, LAC 46:XLV.101 *et seq.*

Physician—an individual who holds a current license or permit duly issued by the board to practice medicine in this state pursuant to R.S. 37:1261-1292.

Licensee—a physician or individual who holds a current license, certificate, registration or permit to practice as an allied health care practitioner as defined herein.

Records or Files of the Case—all relevant information, documents and records gathered in a preliminary review or formal investigation, except board investigator work product or notes, communications with board counsel and other records or files in the board's possession that are required by law to remain confidential or are otherwise privileged, as well as those that independent counsel has ruled need not be included in the records or files of the case following review of the grounds of an objection by the DOI.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292 and 37:1270(A)(5).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2628 (December 2015), amended by the Department of Health, Board of Medical Examiners, LR 46:

§9705. Complaint Origination

A. Complaints may be initiated by any person other than an employee of the board or initiated by the board on its own motion pursuant to R.S. 37:1285.2(A).

B. - C. ...

D. The identity of and communications from a complainant constitute part of the records or files of the case and shall:

1. during a preliminary review, be maintained in confidence by the board. Confidentiality shall be waived only by written authorization of the complainant, when the complainant will be

offered as a witness in a formal administrative hearing before the board or as otherwise provided by law; and

2. after the filing of an administrative complaint pursuant to Chapter 99 of these rules, not remain confidential unless authorized by ruling of independent counsel or the board pursuant to §9905 of these rules.

E. Information received and requested by the board in connection with carrying out its mandated routine regulatory functions e.g., processing applications, receipt and review of reports of medical malpractice settlements or judgments, conducting audits of continuing medical or professional education, site-visits and performance audits, etc., shall not be deemed to be a complaint. However, if such information provides sufficient cause to indicate that a violation of the laws or rules administered by the board may have occurred, such information will be reviewed or investigated in accordance with §9709 or §9711 of this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292 and 37:1270(A)(5) and 37:1285.2.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2628 (December 2015), amended by the Department of Health, Board of Medical Examiners, LR 46:

§9709. Preliminary Review

A. A preliminary review may be initiated to determine if the complaint is jurisdictional and whether sufficient cause exists to warrant formal investigation only upon one or more of the following:

1. a complaint, received from a person, other than an individual employed by the board;

2. a report, received from a law enforcement agency, federal or state regulatory agency, a reporting authority verified by the board through electronic or other means, or a professional health or other monitoring or treatment program, that may implicate a potential violation of the laws or rules administered by the board; and

3. a motion duly adopted by a vote of two-thirds of the members, that sufficient cause exists to indicate a violation of the laws or rules administered by the board may have occurred.

B. A preliminary review is initiated upon the receipt, review and assignment of a case number at the direction of the DOI or the assigned investigator. During a preliminary review such action may be initiated and taken as deemed necessary or appropriate and additional information may be obtained to assist in the determination. As part of the preliminary review:

1. the board may obtain all files and records related to the complaint and to the complainant, which may be needed to determine if the complaint is jurisdictional and whether sufficient cause exists to warrant formal investigation; provided, however, no more than twenty additional files or records of patients may be obtained in connection with the review unless authorized by the board. To assist in a review a designee authorized by the board is authorized to issue, as necessary or upon request of board staff, subpoenas to obtain medical, hospital and pharmacy records and records from law enforcement, state and federal agencies. Affidavits may be obtained to preserve the testimony of a complainant and complaint witnesses;

B.2. - 3.c. ...

C. Any relevant information, documents and records gathered during the preliminary review will be added to the records or files of the case.

D. Preliminary review of a complaint shall be completed as promptly as possible within ninety days of initiation unless extended by the board for satisfactory cause. However, this period

shall not apply to information received from local, state or federal agencies or officials relative to on-going criminal, civil or administrative investigations or proceedings, which do not provide a basis for preliminary review.

E. Nothing in this Chapter requires that a preliminary review be conducted if the complaint is not jurisdictional or information clearly indicates the need for formal investigation or emergent action.

F.-F.2.c. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292 and 37:1270(A)(5) and 37:1285.2.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2628 (December 2015), amended LR 42:571 (April 2016), amended by the Department of Health, Board of Medical Examiners, LR 46:

§9711. Formal Investigation

A. - C. ...

D. Past complaints and investigations of a licensee may be utilized in a current investigation for the purpose of determining if there is a pattern of practice or continuing or recurring conduct that fails to satisfy the prevailing and usually accepted standards of practice in this state on the part of the licensee. If past complaints and investigations are utilized, a licensee and/or his counsel shall be notified and they shall be included within the records or files of the case and subject to all applicable provisions of this Chapter.

E. - F. ...

G. If the investigation provides sufficient information and evidence to indicate that a violation of the law has occurred, an administrative complaint may be filed with the board, pursuant to Chapter 99 of these rules, provided one or more of the following conditions exist:

1. a draft administrative complaint, in the form and content specified in §9903.B of these rules, has been mailed or provided to the licensee accompanied by a letter providing a reasonable opportunity for a conference to show compliance with all lawful requirements for the retention of the license without restriction, or to show that the complaint is unfounded as contemplated by R.S. 49:961(C); however, the licensee fails to respond to the complaint and letter, waives the opportunity, or the response does not satisfactorily demonstrate lawful compliance or that the complaint is unfounded. Such conference may be attended only by the board's director of investigations, the investigator assigned to the matter and legal counsel, if any, compliance counsel, the licensee and the licensee's counsel, if any;

G.2. - H. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292 and 37:1270(A)(5) and 37:1285.2.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2629 (December 2015), amended LR 42:571 (April 2016), amended by the Department of Health, Board of Medical Examiners, LR 46:

§9713. Informal Settlements and Consent Orders

A. - B. ...

C. Informal dispositions may be either non-disciplinary or disciplinary:

1. ...

2. Disciplinary dispositions consist of consent orders, and other orders and agreements, and stipulations for voluntary surrender of a license that are approved by the board as evidenced by the signature of the president or other authorized signatory. These dispositions shall constitute disciplinary action, shall be a public record of the board, and are reported and distributed in the same manner as final decisions of the board. Prior to offering a consent order the DOI shall make available the records or files of

the case pertaining to the complaint against the licensee before the board. Such offer may be transmitted with a proposed consent order provided the individual is advised of his/her opportunity to review the records or files of the case prior to considering the consent order. Unless waived, the licensee may accept this offer any time before signing a consent order.

D. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292 and 37:1270(A)(5) and 37:1285.2.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2629 (December 2015), amended by the Department of Health, Board of Medical Examiners, LR 46:

Chapter 99. Adjudication

§9902. General Definitions

A. The definitions set forth in Chapter 97 of these rules shall equally apply to this Chapter, unless the context clearly states otherwise.

B. In addition, as used in this Chapter, the following additional terms and phrases shall have the meanings specified:

Respondent—a licensee or applicant who is the subject of an administrative enforcement action by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6) and 37:1285.2.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 46:

§9905. Notice of Hearing; Complainant Anonymity

A. - B. ...

C. The notice shall also include the right to be represented by legal counsel of respondent's selection and at his or her cost, and the right to face any complainant at an administrative hearing unless, following a review of all evidence relating to the complaint submitted by the DOI and respondent, independent counsel rules that the complainant may remain anonymous. The ruling of independent counsel relative to complaint anonymity may be overruled by a motion duly adopted by a two-thirds vote of the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B) and 37:1285.2.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 16:507 (June 1990), amended LR 34:1625 (August 2008), repromulgated LR 34:1905 (September 2008), amended by the Department of Health, Board of Medical Examiners, LR 46:

§9916. Discovery; Disclosure

A. After filing and notice of an administrative complaint has been served pursuant to §9905 of this Chapter:

1. - 2. ...

3. the records or files of the case regarding the complaint shall be made available to the respondent through full discovery and disclosed to the respondent at his or her request.

4. Any potential exculpatory evidence shall be disclosed to the respondent whether or not requested and whether or not reduced to recorded or documentary form.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B) and 37:1285.2.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2630 (December 2015), amended by the Department of Health, Board of Medical Examiners, LR 46:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of the proposed Rule amendments on the family has been considered. It is not anticipated that the proposed Rule amendments will have any

impact on family, formation, stability or autonomy, as described in R.S. 49:972.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the impact of the proposed Rule amendments on those that may be living at or below one hundred percent of the federal poverty line has been considered. It is not anticipated that the proposed Rule amendments will have any impact on child, individual or family poverty in relation to individual or community asset development, as described in R.S. 49:973.

Provider Impact Statement

In compliance with HCR 170 of the 2014 Regular Session of the Louisiana Legislature, the impact of the proposed Rule amendments on organizations that provide services for individuals with developmental disabilities has been considered. It is not anticipated that the proposed Rule amendments will have any impact on the staffing, costs or overall ability of such organizations to provide the same level of services, as described in HCR 170.

Small Business Analysis

It is not anticipated that the proposed Rule amendments will have any adverse impact on small businesses as defined in the Regulatory Flexibility Act, R.S. 49:965.2 et. seq.

Public Comments

Interested persons may submit written data, views, arguments, information or comments on the proposed Rule amendments to Rita Arceneaux, Confidential Executive Assistant, Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA 70130, (504) 568-6820, Ex. 242. She is responsible for responding to inquiries. Written comments will be accepted until 4 p.m., January 20, 2020.

Public Hearing

A request pursuant to R.S. 49:953(A)(2) for a public hearing must be made in writing and received by the Board within 20 days of the date of this notice. If a public hearing is requested to provide data, views, arguments, information or comments orally in accordance with the Louisiana Administrative Procedure Act, the hearing will be held on January 27, 2020 at 10 a.m., at the office of the Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA 70130. Any person wishing to attend should call to confirm that a hearing is being held.

Vincent A. Culotta, Jr., M.D.,
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Complaints and Investigations; Adjudication and Practice-Site Visits; Practice Performance Reviews

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed changes will result in a one-time publication expense estimated totaling \$2,023 in FY 20 for the LA State Board of Medical Examiners (LSBME). Furthermore, the proposed rule changes may result in additional costs not anticipated to be significant associated with amending the process for conducting investigations of complaints.

The proposed changes amend rules governing the practice and procedure applicable to physicians and other health care providers licensed by the LSBME who may be the subject of site-visits, practice performance reviews, complaints and investigations and adjudications, to conform them with Act 599 of the 2018 Regular

Session. The proposed changes do the following: align the rules to include presently-regulated allied health care practitioners and define additional terms and amend several existing definitions. They also provide: for complaint origination, complainant confidentiality and routine regulatory functions; instances in which the Board shall initiate a preliminary review; for files and records related to a complaint which the Board may obtain; for records or files of the case; for the duration of a preliminary review and extensions; the use of records from any prior investigation; who may attend conferences associated with investigations; that prior to offering a consent order to a licensee the board shall make all records or files of the case available and for related notice and procedure; for definitions for adjudications; for notice to a licensee of the right to face any complainant at an administrative hearing and for exceptions relative to complainant anonymity; that upon filing of a formal administrative complaint all records or files of the case shall be made available through full discovery and disclosed to respondent at his or her request; disclosure of potential exculpatory evidence; the procedure for initiation of site visits, practice performance reviews or requesting medical records from licensees who are not subject to an active investigation; and make other changes made necessary by the passage of time and/or for purposes of implementation.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule changes will not affect revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

It is not anticipated that the proposed rule amendments will have a significant material effect on costs, paperwork or workload of physicians or allied health care practitioners licensed by the LSBME, nor on receipts and/or income of licensees or non-governmental groups, as the proposed rule changes are procedural in nature. However, because the proposed rule changes significantly amend several processes associated with the LSBME's regulatory functions, physicians and allied health practitioners may realize additional marginal costs that are not anticipated to be significant.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes are not anticipated to affect competition or employment.

Vincent A. Culotta, Jr. M.D.
Executive Director
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Evan Brasseaux
Staff Director
Legislative Fiscal Office